PATENT
Atty. Docket No.: 9009.0009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 5,962,468

Issued: October 5, 1999

To: Chang Y. Hong, Young K. Kim, Se H. Kim, Jay H. Chang, Hoon Choi, Do H. Nam, Ae R. Kim, Jin H. Lee, Ki S. Park

Assignee: LG Life Sciences, Ltd.

For: 7-(4-AMINOMETHYL-3-METHYLOXYIMINOPYRROLIDIN-1-YL)-1-CYCLOPROPYL-6-FLUORO-4-OXO-1,4-DIHYDRO-1,8-NAPHTHYRIDINE-3-CARBOXYLIC ACID AND THE PROCESS FOR THE PREPARATION THEREOF

MAIL STOP: PATENT EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Applicant, LG Life Sciences, Ltd., represents that it is the Assignee of the entire interest in and to United States Patent No. 5,962,468 granted to Chang Y. Hong, Young K. Kim, Se H. Kim, Jay H. Chang, Hoon Choi, Do H. Nam, Ae R. Kin, Jin H. Lee, and Ki S. Park on the 5th day of October, 1999, for 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid and the process for the preparation thereof by virtue of an assignment in favor of LG Life Sciences, Ltd. An assignment from the inventors to LG Chemical Ltd. was recorded at Reel 007531, Frame 0413 on June 15, 1995. A document indicating a change in name from LG Chemical Ltd. to LG Chem Investment, Ltd. was recorded at Reel

013563, Frame 0644 on December 11, 2002. An assignment from LG Chem Investment, Ltd. to LG Life Sciences, Ltd. was recorded at Reel 013570, Frame 0131 on December 11, 2002. By the Power of Attorney enclosed herein (Attachment A), Applicant appoints attorneys at Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., associated with Customer No. 22852, including Charles E. Van Horn, Andrew C. Sonu and Steven P. O'Connor, as attorneys for LG Life Sciences, Ltd. with regard to this application for extension of the term of U.S. Patent 5,776,944 and to transact all business in the U.S. Patent and Trademark Office in connection therewith.

Information Required Under 37 C.F.R. § 1.740

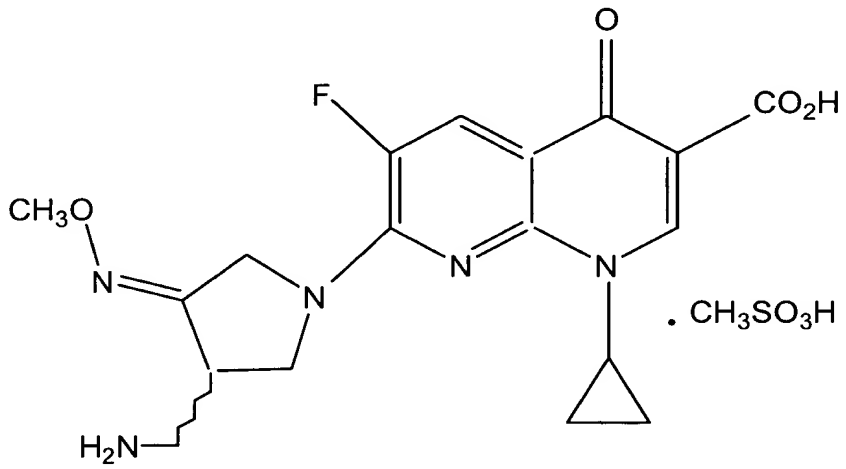
Applicant hereby submits this application for extension of the patent term under 35 U.S.C. § 156 by providing the following information required by the rules promulgated by the U.S. Patent and Trademark Office (37 C.F.R. § 1.740). For the convenience of the Patent and Trademark Office, the information contained in this application will be presented in a format which follows the requirements of Section 1.740 of Title 37 of the Code of Federal Regulations.

(1) The approved product FACTIVE® is a broad spectrum antibacterial agent for oral administration containing gemifloxacin mesylate as the active ingredient. Gemifloxacin is available as the mesylate salt in the sesquihydrate form. Identification of gemifloxacin is as follows:

Chemical Name(s): (*R,S*)-7-[(4Z)-3-(aminomethyl)-4-(methoxyimino}-1-pyrrolidinyl]-1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-1,8-naphthyridine-3-carboxylic acid

Empirical Formula of gemifloxacin mesylate: $C_{18}H_{20}FN_5O_4 \bullet CH_4O_3S$

Structural Formula of gemifloxacin mesylate:



(2) The approved product was subject to regulatory review under the Federal Food, Drug and Cosmetic Act Section 505.

(3) The approved product FACTIVE® received permission for commercial marketing or use under Section 505 of the Federal Food, Drug and Cosmetic Act on April 4, 2003. A copy of the approval letter is attached (Attachment B).

(4) The active ingredient in FACTIVE® is gemifloxacin mesylate available in the sesquihydrate form which, on information and belief, has not been approved for commercial marketing or use under the Public Health Services Act, the Virus-Serum-Toxin Act or under Section 505 of the Federal Food, Drug and Cosmetic Act prior to the approval of NDA 21-158 by the Food and Drug Administration on April 4, 2003. A copy of the approved labeling information describing the approved product is attached (Attachment C).

(5) This application for extension of patent term under 35 U.S.C. § 156 is being submitted within the permitted 60-day period pursuant to 37 C.F.R. § 1.720(f), said period will expire on June 3, 2003.

(6) The complete identification of the patent for which a term extension is being sought is as follows:

Inventors: Chang Y. Hong, Young K. Kim, Se H. Kim,
Jay H. Chang, Hoon Choi, Do H. Nam,
Ae R. Kim, Jin H. Lee, Ki S. Park

Patent No.: 5,962,468

Issue Date: October 5, 1999

Expiration Date: June 15, 2015

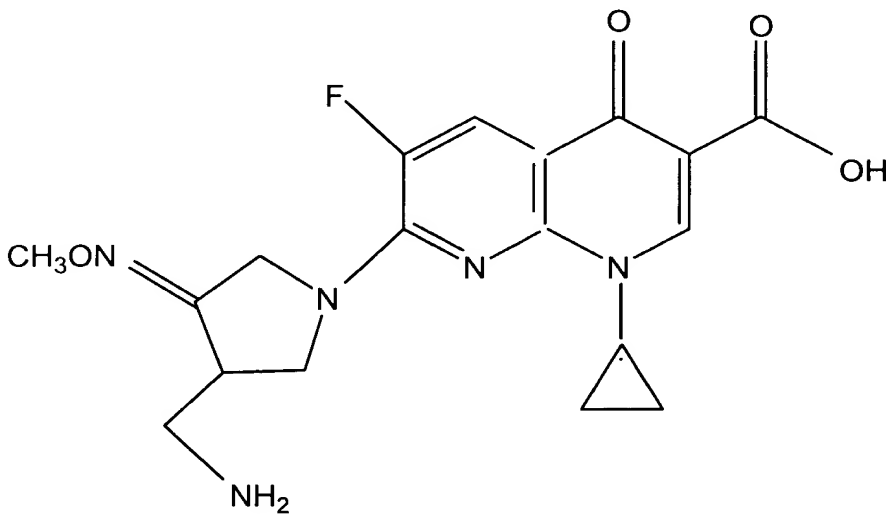
(7) A true copy of the patent is attached (Attachment D).

(8) No reexamination certificate has been issued on this patent. LG Life Sciences, Ltd. filed a request for reexamination of U.S. Patent No. 5,962,468 on December 27, 2002, which was granted by the U.S. Patent and Trademark Office by

an Order mailed March 12, 2003. The reexamination control number is 90/006,499. A copy of a Certificate of Correction and a record of maintenance fee payment under 35 U.S.C. § 41(b) are attached (Attachment E).

(9) Claims 1-12 of U.S. Patent 5,962,468 claim methods for prophylaxis or treatment of bacterial infections in warm blooded animals comprising administering the active ingredient in FACTIVE®.

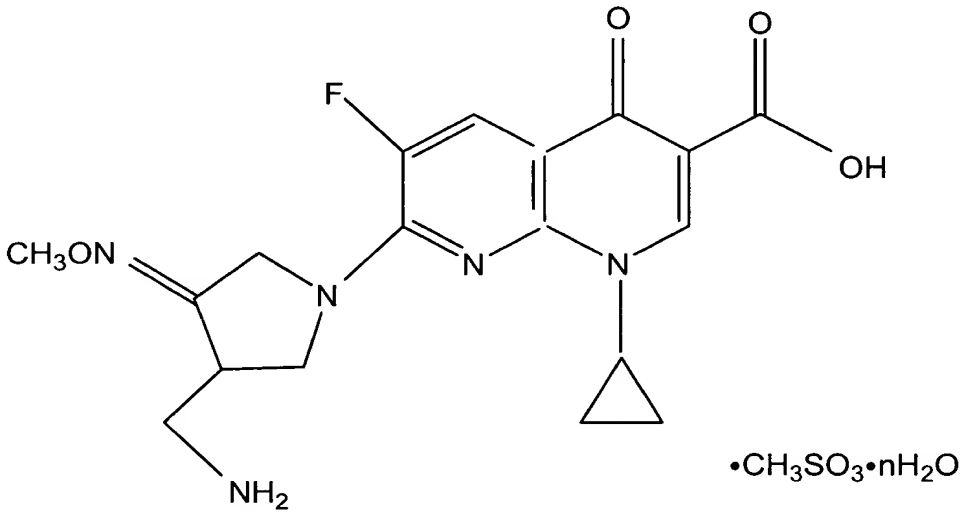
(a) Claim 1 reads as follows: "A method for prophylaxis or treatment of bacterial infections in a warm blooded animal, comprising administering an effective amount of the compound 7-(4-aminomethyl-3-methyloxylminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid of the following formula:



or a pharmaceutically acceptable non-toxic salt, physiologically hydrolyzable ester, or isomer thereof."

Claim 1 reads on an approved use of the approved product FACTIVE® because FACTIVE® has been approved for the treatment of acute bacterial exacerbation of chronic bronchitis and community-acquired pneumonia in humans.

(b) Claim 5 reads as follows: "A method for prophylaxis or treatment of bacterial infections in a warm blooded animal, comprising administering an effective amount of the compound 7-(4-aminomethyl-3-methyloxylminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid methanesulfonate or a hydrate thereof of the following formula:



in which n is 0, 1.5, 2.5, 3, 3.5, or 4, or an isomer thereof."

Claim 5 reads on an approved use of the approved product FACTIVE® because when n = 1.5 it reads on the sesquihydrate form of the active ingredient of FACTIVE® and FACTIVE® has been approved for the treatment of acute bacterial exacerbation of chronic bronchitis and community-acquired pneumonia in humans.

(10) The relevant dates and information pursuant to 35 U.S.C. § 156(g) to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

Investigational New Drug Application (IND 53,908) for FACTIVE® was submitted on August 6, 1997, received on August 7, 1997, and became effective on September 6, 1997.

New Drug Application for FACTIVE® (NDA 21-158) was submitted on December 15, 1999.

New Drug Application for FACTIVE® (NDA 21-158) was approved on April 4, 2003.

(11) A brief description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to FACTIVE® and the dates applicable to these significant activities are set forth in a chronology of events in Attachment F.

(12)(i) Applicant is of the opinion that U.S. Patent 5,962,468 is eligible for extension of the patent term under 35 U.S.C. § 156 because it satisfies all requirements for such extension as follows:

(a) 35 U.S.C. § 156(a) - U.S. Patent 5,962,468 claims a method of prophylaxis or treatment by administering a drug product, that is, the active ingredient in FACTIVE®.

(b) 35 U.S.C. § 156(a)(1) - U.S. Patent 5,962,468 has not expired before submission of this application.

(c) 35 U.S.C. § 156(a)(2) - The term of U.S. Patent 5,962,468 has never been extended under 35 U.S.C. § 156(e)(1).

(d) 35 U.S.C. § 156(a)(3) - The application for extension is submitted by the owner of record of the patent in accordance with the requirements of paragraphs (1) through (4) of 35 U.S.C. § 156(d) and the rules of the Patent and Trademark Office.

(e) 35 U.S.C. § 156(a)(4) - The product FACTIVE® has been subjected to a regulatory review period before its commercial marketing or use.

(f) 35 U.S.C. § 156(a)(5)(A) - The commercial marketing or use of the product FACTIVE® after the regulatory review period is the first permitted commercial marketing or use under the provision of the Federal Food, Drug and Cosmetic Act (*i.e.*, Section 505) under which such regulatory review period occurred.

(g) 35 U.S.C. § 156(c)(4) - No other patent has been extended for the same regulatory review period for the product FACTIVE®. Applicant has filed two other applications for term extension (U.S. Patent Nos. 5,633,262 and 5,776,944) based on the regulatory review period for the product FACTIVE. Applicant will make an election of only one patent in accordance with 37 CFR 1.785(b) upon receipt of a notice of final determination in these applications from the Patent and Trademark Office.

(12)(ii) Applicant respectfully submits that the length of the extension of patent term for U.S. Patent 5,962,468 is 659 days pursuant to 35 U.S.C. § 156(c). The length of the extension was determined pursuant to 37 C.F.R. § 1.775 as follows:

(a) The regulatory review period under 35 U.S.C. § 156(g)(1)(B) began on September 6, 1997 and ended on April 4, 2003, which is a total of 2038 days, which is the sum of (1) and (2) below:

(1) The period of review under 35 U.S.C. § 156(g)(1)(B)(i), the "Testing Period", began on September 6, 1997 and ended on December 15, 1999, which is 831 days; and

(2) The period of review under 35 U.S.C. § 156(g)(1)(B)(ii), the "Approval Period", began on December 15, 1999, and ended on April 4, 2003, which is a total of 1207 days.

(b) The regulatory review period upon which the period of extension is calculated is the entire regulatory review period as determined in subparagraph 12(ii)(a) above (2038) less:

(1) The number of days in the regulatory review period which were on or before the date on which the patent issued (October 5, 1999) which is 759 days; and

(2) The number of days during which applicant did not act with due diligence, which is zero (0) days; and

(3) One-half the number of days determined in subparagraph (12)(ii)(a)(1) above after the patent issued (one-half of 72) which is 36 days;

(c) The number of days as determined in subparagraph (12)(ii)(b) (1243 days) when added to the original term of the patent (June 15, 2015) would result in the date of November 15, 2018.

(d) Fourteen (14) years when added to the date of the NDA approval (April 4, 2003) would result in the date of April 4, 2017;

(e) The earlier date as determined in subparagraphs (12)(ii)(c) and (12)(ii)(d) is April 4, 2017;

(f) Since the patent for FACTIVE® issued after September 24, 1984, the period of extension may not exceed five years from the original expiration date of June 15, 2015. Five years when added to the original expiration date of the patent would result in the date of June 15, 2020.

(g) The earlier date as determined by subparagraphs (12)(ii)(e) and (12)(ii)(f) is April 4, 2017.

(13) Applicant acknowledges a duty to disclose to the Director of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

(14) The prescribed fee for receiving and acting upon this application is attached as a check in the amount of $1,120.00. The Commissioner is authorized to charge any additional fees required by this application to Deposit Account No. 06-0916.

(15) All correspondence and inquiries may be directed to the undersigned, whose address, telephone number and fax number are as follows:

Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, D.C. 20005-3315
Phone: 202-408-4000
Fax: 202-408-4400

(16) Enclosed is a certification that the application for extension of patent term under 35 U.S.C. § 156 including its attachments and supporting papers is being submitted as one original and four (4) copies thereof (Attachment G).

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: Charles E. Van Horn
Charles E. Van Horn
Reg. No. 40,266

Date: May 29, 2003

Attachments:
Power of Attorney (Attachment A)
Approval Letter (Attachment B)
Approved Labeling Information for FACTIVE® (Attachment C)
U.S. Patent 5,962,468 (Attachment D)
Certificate of Correction and Maintenance Fees Paid (Attachment E)
Chronology of Regulatory Review Period (Attachment F)
Certification of Copies of Application Papers (Attachment G)